

PHARMACEUTICALS

by William Hurt and Marnie Morrione

Chemicals, Pharmaceuticals, and Biotechnology, Trade Development

The pharmaceutical industry is unique among U.S. industry sectors. The industry is consistently ranked one of the top performing industries. *Fortune* ranked the pharmaceutical industry as best performer in 2001. Large, diversified, and global, the U.S. pharmaceutical industry plays a crucial role in the U.S. economy. According to the *IMS Market Prognosis International 2002-2006 Report*, the U.S. market for pharmaceuticals will reach \$330 billion by 2006. The U.S. pharmaceutical market is expected to grow by almost 12 percent yearly between 2000 and 2005. Research-based companies currently have more than 1,000 medicines in the pipeline. Also, since 1984, generic drug companies' share of the prescription drug industry has grown from 19 percent to 47 percent. Economists predict that by 2005 generics will account for 57 percent of the market by volume.

On a global scale, the United States is expected to be the engine for growth in the world pharmaceutical market between 2002 and 2005. Global sales of prescription drugs (including both branded and generics) and over-the-counter (OTC) remedies top \$300 billion annually. Due to innovation, the United States will increase its dominance of the global pharmaceutical market to 60.5 percent by 2005 according to IMS health reports.

The international market for pharmaceuticals offers a wealth of potential for U.S. companies and is expected to grow at 7.8 percent annually to \$406 billion in 2002. Key factors fueling the

expansion include strong demographic gains of the elderly, rising living standards in developing nations, and intensified global R&D activity, which should generate a steady flow of new therapeutic products. During the next five years, the fastest growing regions are expected to be North America, the Middle East, and Asia.

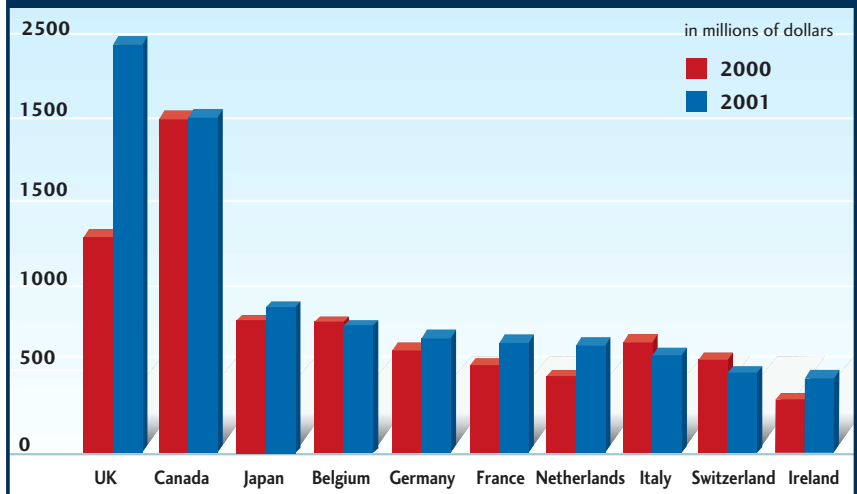
With all its accomplishments the U.S. pharmaceutical industry has some serious vulnerabilities: its public image; its relationship with international organizations; international property violations; and market barriers. If these problems are not addressed, they could lead to major losses of market share and a weakening of the industry's economic success and innovation. The Commerce Department is working on all of these areas to promote international trade for the U.S.

pharmaceutical industry and to expand export opportunities. The pharmaceutical industry must remain healthy, since it is not only a significant contributor to the U.S. and world economies, but also a player in improving global health.

PUBLIC IMAGE

While the U.S. pharmaceutical industry has done an outstanding job marketing its products, it has done a poor job in marketing itself. The message has not been conveyed on all the good work the industry offers. The U.S. pharmaceutical industry does more philanthropic work than any other domestic industry sector. From 1996 to 2000, America's pharmaceutical companies gave more than \$1 billion in health and infrastructure donations

TOP MARKETS FOR EXPORTS OF PHARMACEUTICAL PRODUCTS BY VALUE





AIDS testing equipment.

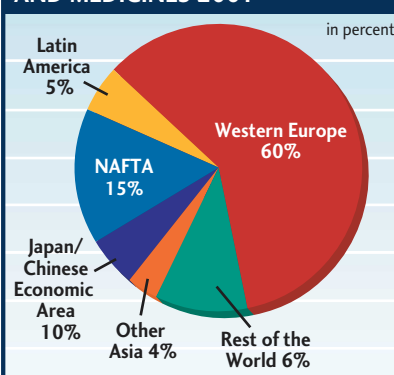
to the developing world. Many of the pharmaceutical companies have also begun to tackle the HIV/AIDS crisis by contributing to prevention and treatment programs. For example: Merck donated funding and medicine to the Botswana Comprehensive HIV/AIDS Partnership to improve HIV/AIDS education; Bristol-Myers Squibb contributed \$115 million through its Secure the Future program, which supports orphans, women, and children with HIV/AIDS in sub-Saharan Africa; and, Pfizer funded the Academic Alliance for AIDS Care and Prevention to build, operate, and equip AIDS treatment and prevention centers in Uganda. These are just a few of the philanthropic efforts. In all, the pharmaceutical industry has a positive impact on humanitarian efforts in more than 100 developing countries around the world. Commerce is starting to work with industry representatives, trade associations, and international organizations to highlight the contributions U.S. industry is making to world health. On June 24, Commerce Secretary Don Evans joined Secretary of State Colin Powell and other U.S. government officials at the Conference on the Role of Public-Private Partnerships in the Global Fight against HIV/AIDS, to emphasize the important role the private sector plays in combating AIDS worldwide.

INTERNATIONAL ORGANIZATIONS

As the industry becomes more global, and health and trade issues become more interwoven, international organizations take on a new importance. For example, the World Health Organization (WHO) is playing a critical role in shaping the multibillion-dollar international health market in which U.S. pharmaceutical companies operate. U.S. pharmaceutical companies have concerns that some WHO policies are creating an uneven playing field for the United States in the international arena. U.S. companies are concerned that the WHO does not hear or consider their views regarding issues such as the WHO's Essential Drug List, global pricing, and quality control.

The Department of Commerce (DOC), in collaboration with other federal agencies, is working to increase communication with the WHO regarding health and trade issues, and to initiate discussions between the WHO and the private sector. For the first time, the DOC participated as a member of the U.S. delegation in the World Health Assembly of the WHO in Geneva, Switzerland, May 13-18, 2002. The

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Source: ITA/OTEA/Trade Patterns Tables, May 2002

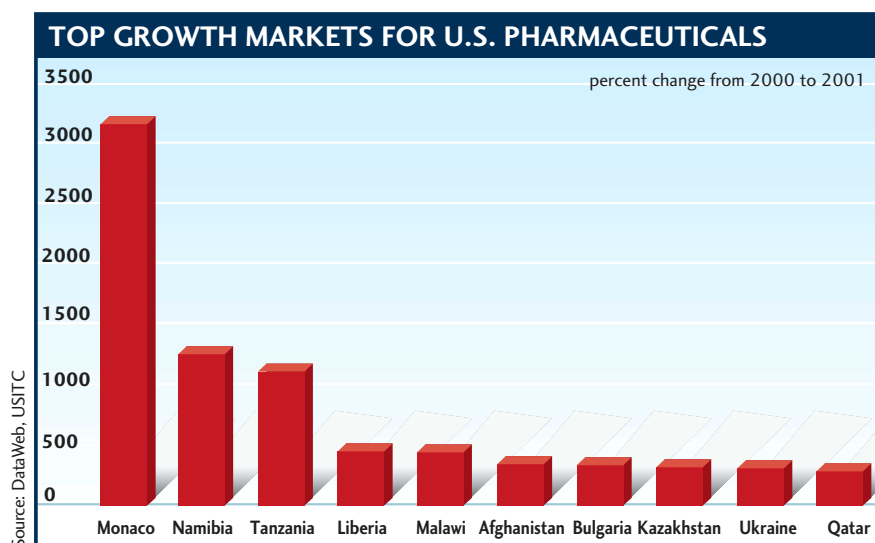
main function of the assembly is to determine the policies of the WHO. Assistant Secretary for Trade Development Linda Conlin represented the DOC at the assembly. She also met with WHO officials, private-sector groups, and non-governmental organizations to discuss how increased collaboration between the various sectors might move forward some of the ideas on how to improve global health.

Another international initiative that impacts the U.S. pharmaceutical industry but also provides opportunities is the Global Fund to Fight AIDS, Tuberculosis and Malaria, proposed by U.N. Secretary-General Kofi Annan



Photo courtesy of U.S. Mission, Geneva

Linda Conlin, Assistant Secretary for Trade Development, Raymond Gilmartin, Chairman, President, and CEO of Merck & Co., and Dr. George A.O. Alleyne, Director, Pan American Health Organization gather at the World Health Assembly in Geneva, Switzerland.



and strongly supported by the United States. The United States has pledged \$500 million to the fund to date. The DOC has been working with Health and Human Services, the State Department, U.S. Agency for International Development, and other federal agencies to assist in the fund's development. The U.S. government and Commerce believe the fund represents a unique opportunity for public-private partnerships to provide grants for prevention, treatment, and care. Not only does the fund provide money for purchasing medicines, but it also provides possibilities for the private sector to offer assistance with infrastructure, technical knowledge, distribution systems, and education.

INTELLECTUAL PROPERTY RIGHTS

Strong intellectual property protection is essential for research and innovation, and it creates incentives for further investment and technological progress worldwide. On November 14, 2001, in Doha, Qatar, the member countries of the World Trade Organization (WTO) adopted a "political declaration" on public health and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). The declaration confirms that all member countries can avail themselves

of the flexibility inherent in TRIPs to address public health emergencies, such as epidemics of HIV/AIDS, tuberculosis, and malaria.

The Doha declaration left unresolved one issue of concern to developing and least-developed countries with respect to compulsory licensing and access to pharmaceuticals. The declaration recognized that certain WTO members could have difficulty using the compulsory licensing provisions of the TRIPs agreement when there is no producer in the country to produce the pharmaceutical to be licensed. The TRIPs Council must find an expeditious solution to this problem and report to the General Council of the WTO before the end of 2002. The DOC is working with the Office of the U.S. Trade Representative and other federal agencies to develop an acceptable solution.

MARKET ACCESS AND REGULATORY BARRIERS

In 2001, Pharmaceutical Research and Manufacturers of America (PhRMA) estimated that trade barriers — particularly inadequate intellectual property protection for pharmaceuticals and price controls — cost U.S. drug firms \$11 billion a year. Market access barriers encountered by the U.S.

pharmaceutical industry are common. The DOC has recently been involved with cases in countries such as Brazil, China, South Korea, Croatia, Italy, Japan, Spain, Turkey, and Taiwan.

In order to address the growing problem of trade barriers, the DOC continues to encourage increased government-industry dialogue on market access concerns to develop positions for a variety of bilateral and multilateral initiatives. These initiatives include, among others, the U.S.-China Joint Commission on Commerce and Trade, the U.S.-Russia Cooperation Council, the Transatlantic Business Dialogue, and the Free Trade Agreement of the Americas.

The challenges that the world community faces in providing adequate health care and improvements in quality of life are also opportunities for U.S. companies to rise to the occasion and contribute new technologies and life-saving pharmaceuticals to enhance the well-being of all. ■